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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 904,756	07 13 2001	William V. Curran	8067-094-999	3899

500 7590 02 28 2003

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EXAMINER

RUSSELL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 02 28 2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,756

Applicant(s)

CURRAN ET AL

Examiner

Jeffrey E Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21-24, 26-31, 34-38 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 20, 25, 32, 33 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8,9
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

Art Unit: 1654

1. The disclosure is objected to because of the following informalities: If the application serial number can be inserted at page 34, line 1, of the specification consistent with the guidelines of MPEP 608.01(p)(I)(A) and *In re Fouche*, 169 USPQ 429 (CCPA 1971) cited therein, the serial number should be inserted therein. Otherwise, the reference to a specific U.S. patent application should be deleted. The status of the U.S. application referred to at page 35, line 11, of the specification should be updated. Appropriate correction is required.

2. Claims 13, 14, 18, 21, 22, 26, 34, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "and" should be inserted before "(L4)" at claim 13, page 60, line 1, so that standard Markush terminology is used. There is no antecedent basis in the claims for the phrase "The compound of Claim 17" at claim 18, line 1. Note that claim 17 is drawn to an antimicrobial sulfonamide derivative, not a compound. For analogous reasons, claims 21, 34, and 36 are also indefinite because of lack of antecedent basis. Claims 18 and 21 are indefinite because they define a variable Y^2 which is not used in any structural formula in the claims. It is believed that this variable should instead be "Y". Claim 22 is indefinite because the variables S^2 and S^3 are not defined in the claim. Claim 26 is indefinite because the variables S^2 , S^3 , and S^4 are not defined in the claim.

3. Claims 1, 2, and 4-42 are objected to because of the following informalities: At claim 1, lines 5-6, the phrase "core cyclic antibiotic" should be changed to "core antibiotic" so that the terminology is consistent with that used at line 3 of the claim. At claim 4, line 6, "each" should not be capitalized. At claim 4, line 7, the end parenthesis after " R^1 " should not be a superscript. Claims 15, 22, and 26 do not end with periods. At claim 37, line 2; claim 41, page 64, line 3;

Art Unit: 1654

and claim 42, lines 2 and 3; "an" should be changed to "a". At claim 37, line 3; claim 38, line 1; claim 41, page 64, line 4; and claim 42, line 5; "a" should be changed to "an". Appropriate correction is required.

4. Claim 33 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 33 recites that R is a core cyclic peptide, whereas claim 32, upon which claim 33 depends, recites that R is a core antibiotic. However, as defined in the specification (see pages 5-11), a core cyclic peptide and a core antibiotic have different structures and the former is not a subset or species of the latter. Accordingly, claim 33 does not further limit claim 32. It is believed that claim 33 should instead depend upon claim 30. Claim 40 requires the lipophilic sulfonyl derivative to be a lipophilic sulfonyl chloride, whereas claim 39, upon which claim 40 depends, requires the lipophilic sulfonyl derivative to be a lipophilic sulfonyl ester. It is believed that claim 40 should instead depend upon claim 38.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1654

6. Claims 1, 3-17, 19, 22-24, 26-29, and 34-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-65, 69-71 of U.S. Patent No. 6,511,962. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '962 patent anticipate the instant claims. The '962 patent claims laspartomycin derivatives in which X^1 can be $-SO_2-$, thereby forming a sulfonamide group (see column 44, line 2, and column 45, line 2), or in which X^2-X^3 can be a sulfonamide group (see column 44, lines 59-60, and column 46, lines 30-31).

7. Claims 1, 3-17, 19, 22-24, 26-29, and 34-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-71, 73, 74, 76, 77, and 79 of copending Application No. 09/904,352. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '352 application anticipate the instant claims. The '352 application claims laspartomycin derivatives in which X^1 can be $-SO_2-$, thereby forming a sulfonamide group (see claim 49), or in which X^2-X^3 can be a sulfonamide group (see claims 51 and 66).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 3-17, 19, 22-24, 26-29, and 34-36 are directed to an invention not patentably distinct from claims 43-65 and 69-71 of commonly assigned U.S. Patent No. 6,511,962. Specifically, see the above obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. Patent No. 6,511,962, discussed above, would form the basis for a

Art Unit: 1654

rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

9. Claims 1, 3-17, 19, 22-24, 26-29, and 34-36 are directed to an invention not patentably distinct from claims 49-71, 73, 74, 76, 77, and 79 of commonly assigned U.S. Patent Application 09/904,352. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. Patent Application 09/904,352, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in

Art Unit: 1654

this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

10. The effective filing date of instant claims 1 and 3 is deemed to be at least January 12, 2001, the filing date of parent application 09/760,328. Instant claims 1 and 3 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/760,328 because the parent application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention. The effective filing date of instant claims 2 and 4-42 is deemed to be July 13, 2001, the filing date of the instant application. Instant claims 2 and 4-42 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/760,328 because the parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose antimicrobial sulfonamide derivatives in general in which the linking chain is a sulfonamide linkage; does not disclose compounds of structural Formula (I), e.g., does not disclose the full range of $X-N(R^4)$ substituents, does not disclose the embodiments in which $m=0$, and does not disclose alkyl groups of the size recited in the definitions of R^1 and R^4 ; does not disclose all of the core cyclic peptides or core antibiotics of instant claims 5-8, e.g., does not disclose brevistin, cerexin A or B, or Antibiotic A-30912; does not disclose a substituent corresponding to R^6 in instant claim 13 in which the variable can comprise an 11- to 16-membered heteroaryl; and does not disclose the synthesis method involving lipophilic sulfonyl derivatives as is recited in instant

Art Unit: 1654

claims 37-42. Accordingly, U.S. Patent No. 6,511,962, which issued based upon parent application 09/760,328 and has a different inventorship than the instant application, is available as prior art against instant claims 2 and 42 under 35 U.S.C. 102(e).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 4-17, 19, 22-24, 26-29, and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,511,962. See the above obviousness-type double patenting rejection. In addition, see column 27, structures 101 and 106.

13. Claims 1-4, 11-17, 22, 26, 30, 31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouchaudon et al (U.S. Patent No. 3,817,973). Bouchaudon et al teach antibiotic compounds in which X can be SO₂, i.e. in which the compounds can comprise a sulfonamide group, and in which A is an alkyl of 3-18 carbon atoms, i.e. is a lipophilic moiety. See, e.g., the Abstract; column 24, lines 38-41; and column 25, lines 23-38. For example, with respect to instant claim 22, the sidechain of the Dab residue to which X is attached in the patent's polymyxins corresponds to Applicants' S² group, and the sidechain of the adjacent Thr residue corresponds to Applicants' S³ group.

14. Claims 1-4, 12, 30, 31, 34-38, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/00173. The WO Patent Application '173 teaches a

Art Unit: 1654

drug, which can be an antibiotic, conjugated through a sulfonamide group to an optionally substituted phenyl or 5- or 6-membered heterocyclic ring. The drug can be reacted with the appropriate sulfonyl chloride in order to form the final conjugated product. See, e.g., page 7, line 35 - page 8, line 5; page 14, line 34 - page 15, line 10; page 23, lines 9-12; and page 33, line 1.

15. Claims 20, 25, 32, 33, and 39 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 18 and 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or fairly suggest compounds having the structures recited in instant claims 18, 20, 21, 25, 32, and 33. Bouchaudon et al do not suggest that their sulfonamide groups have general utility in derivatizing antimicrobial agents in general, and the WO Patent Application '173 does not suggest the particular cyclic peptides or lipopeptide antibiotics specified in these claims. With respect to claim 39, neither Bouchaudon et al nor the WO Patent Application '173 teach or suggest reactions using a lipophilic hydroxybenzotriazole ester intermediate.

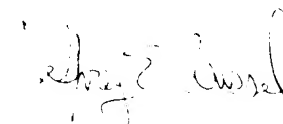
Bauer et al (U.S. Patent No. 4,435,385) is cited as art of interest, teaching a compound comprising a lipophilic group attached through a sulfonamide group to a cyclic peptide (see column 9, Example No. 13). However, there is no teaching or suggestion in Bauer et al that the compound may have antimicrobial activity (compare, e.g., column 11, lines 27-39), and the compound of Bauer et al is not similar enough in structure to the specific compounds disclosed by Applicants in order to establish prima facie anticipation on the basis of inherency.

Art Unit: 1654

No provisional rejection under 35 U.S.C. 102(e) is made over U.S. Patent Application 09/904,352, applied above, because such a rejection would be duplicative of the actual rejection under 35 U.S.C. 102(e) over U.S. Patent No. 6,511,962 set forth above.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 27, 2003